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## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

|   |                            |   |    |           |                           |    |            |                            |    |  |
|---|----------------------------|---|----|-----------|---------------------------|----|------------|----------------------------|----|--|
| (51) International Patent Classification <sup>6</sup> :<br><br>A61K 31/365  | A3                         | (11) International Publication Number: WO 98/01100<br><br>(43) International Publication Date: 15 January 1998 (15.01.98) |    |           |                           |    |            |                            |    |  |
| <p>(21) International Application Number: PCT/US97/11792</p> <p>(22) International Filing Date: 3 July 1997 (03.07.97)</p> <p>(30) Priority Data:</p> <table border="0"><tr><td>60/021,420</td><td>9 July 1996 (09.07.96)</td><td>US</td></tr><tr><td>9617898.3</td><td>28 August 1996 (28.08.96)</td><td>GB</td></tr><tr><td>60/029,351</td><td>31 October 1996 (31.10.96)</td><td>US</td></tr></table> <p>(71) Applicant (for all designated States except US): MERCK &amp; CO., INC. (US/US); 126 East Lincoln Avenue, Rahway, NJ 07065 (US).</p> <p>(72) Inventors; and<br/>(75) Inventors/Applicants (for US only): MITCHEL, Yale, B. (US/US); 126 East Lincoln Avenue, Rahway, NJ 07065 (US). TOBERT, Jonathan, A. (US/US); 126 East Lincoln Avenue, Rahway, NJ 07065 (US).</p> <p>(74) Common Representative: MERCK &amp; CO., INC.; 126 East Lincoln Avenue, Rahway, NJ 07065 (US).</p> | 60/021,420                 | 9 July 1996 (09.07.96)  | US | 9617898.3 | 28 August 1996 (28.08.96) | GB | 60/029,351 | 31 October 1996 (31.10.96) | US | <p>(81) Designated States: AL, AM, AU, AZ, BA, BB, BG, BR, BY, CA, CN, CU, CZ, EE, GE, HU, IL, IS, JP, KG, KR, KZ, LC, LK, LR, LT, LV, MD, MG, MK, MN, MX, NO, NZ, PL, RO, RU, SG, SI, SK, SL, TJ, TM, TR, TT, UA, US, UZ, VN, YU, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).</p> <p>Published<br/><i>With international search report.<br/>Before the expiration of the time limit for amending the claims<br/>and to be republished in the event of the receipt of amendments.</i></p> <p>(88) Date of publication of the international search report:<br/>12 February 1998 (12.02.98)</p> |
| 60/021,420  | 9 July 1996 (09.07.96)     | US  |    |           |                           |    |            |                            |    |  |
| 9617898.3   | 28 August 1996 (28.08.96)  | GB  |    |           |                           |    |            |                            |    |  |
| 60/029,351  | 31 October 1996 (31.10.96) | US  |    |           |                           |    |            |                            |    |  |
| <p>(54) Title: METHOD FOR TREATING HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA</p> <p>(57) Abstract</p> <p>Homozygous familial hypercholesterolemia can be treated in patients suffering with this condition by administering a therapeutically effective amount of simvastatin. Dosages above 40 mg/day, and more particularly at or above 80 mg/day, were found to effectively reduce the LDL cholesterol levels in these patients.</p>  |                            |   |    |           |                           |    |            |                            |    |  |

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## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US97/11792

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61K 31/365

US CL :514/460

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 514/460

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

CHEMICAL ABSTRACTS

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages   | Relevant to claim No. |
|-----------|--|-----------------------|
| X         | Randomised trial of cholesterol lowering in 4444 patients with coronary heart disease: the Scandinavian Simvastatin Survival Study (4S). Lancet. November 1994, Vol. 19:344, pages 1383-9 (1994) (Abstract). | 1-9                   |
| A         | US, 5,393,893 A (KUBELA et al.) 28 February 1995, see entire document.   | 1-9                   |
| A         | US, 4,997,849 A (PETUCH et al.) 05 March 1991, see entire document.  | 1-9                   |

☐ Further documents are listed in the continuation of Box C.
 ☐ See patent family annex.

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| *P* | document published prior to the international filing date but later than the priority date claimed  |     |  |

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Facsimile No. (703) 305-3230

Authorized officer

JAMES H. REAMER

Telephone No. (703) 308-1235

185/39/61

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13245748

Basic Patent (No,Kind,Date): GB 9617898 A0 19961009 <No. of Patents: 007>

Patent Family:

| Patent No  | Kind | Date     | Applic No    | Kind | Date     |         |
|------------|------|----------|--------------|------|----------|---------|
| AU 9736672 | A1   | 19980202 | AU 9736672   | A    | 19970703 |         |
| AU 9742289 | A1   | 19980202 | AU 9742289   | A    | 19970703 |         |
| AU 9743261 | A1   | 19980202 | AU 9743261   | A    | 19970703 |         |
| GB 9617898 | A0   | 19961009 | GB 9617898   | A    | 19960828 | (BASIC) |
| WO 9801116 | A1   | 19980115 | WO 97US12426 | A    | 19970703 |         |
| WO 9801100 | A2   | 19980115 | WO 97US11792 | A    | 19970703 |         |
| WO 9801119 | A2   | 19980115 | WO 97US10867 | A    | 19970703 |         |

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GB 9617898 A 19960828  
US 21420 P 19960709  
US 29351 P 19961031  
WO 97US12426 W 19970703  
WO 97US11792 W 19970703

WO 97US10867 W 19970703

PATENT FAMILY:

AUSTRALIA (AU)

Patent (No,Kind,Date): AU 9736672 A1 19980202  
THERAPY FOR COMBINED HYPERLIPIDEMIA (English)  
Patent Assignee: MERCK & CO INC  
Author (Inventor): MITCHEL YALE B; MELINO MICHAEL R  
Priority (No,Kind,Date): GB 9617898 A 19960828; US 21420 P  
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Applic (No,Kind,Date): AU 9736672 A 19970703  
IPC: \* A61K-009/20  
CA Abstract No: \* 128(09)097715J; 128(09)097716K; 128(11)132435S  
Derwent WPI Acc No: \* C 98-110203; C 98-110207; C 98-145191  
Language of Document: English  
Patent (No,Kind,Date): AU 9742289 A1 19980202  
METHOD FOR TREATING HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (English)  
Patent Assignee: MERCK & CO INC  
Author (Inventor): MITCHEL YALE B; TOBERT JONATHAN A  
Priority (No,Kind,Date): GB 9617898 A 19960828; US 21420 P  
19960709; US 29351 P 19961031; WO 97US11792 W 19970703  
Applic (No,Kind,Date): AU 9742289 A 19970703  
IPC: \* A61K-031/00  
CA Abstract No: \* 128(09)097715J; 128(09)097716K; 128(11)132435S  
Derwent WPI Acc No: \* C 98-110203; C 98-110207; C 98-145191  
Language of Document: English  
Patent (No,Kind,Date): AU 9743261 A1 19980202  
PHARMACEUTICAL COMPOSITIONS (English)  
Patent Assignee: MERCK & CO INC  
Author (Inventor): MITCHEL YALE B; TOBERT JONATHAN A  
Priority (No,Kind,Date): GB 9617898 A 19960828; US 21420 P  
19960709; US 29351 P 19961031; WO 97US10867 W 19970703  
Applic (No,Kind,Date): AU 9743261 A 19970703  
IPC: \* A61K-031/00  
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Derwent WPI Acc No: \* C 98-110203; C 98-110207; C 98-145191  
Language of Document: English

GREAT BRITAIN (GB)

Patent (No,Kind,Date): GB 9617898 A0 19961009  
METHOD FOR TREATING HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (English)  
Patent Assignee: MERCK & CO INC  
Priority (No,Kind,Date): GB 9617898 A 19960828  
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WORLD INTELLECTUAL PROPERTY ORGANIZATION, PCT (WO)

Patent (No,Kind,Date): WO 9801116 A1 19980115  
THERAPY FOR COMBINED HYPERLIPIDEMIA (English)  
Patent Assignee: MERCK & CO INC (US); MITCHEL YALE B (US); MELINO  
MICHAEL R (US)  
Author (Inventor): MITCHEL YALE B (US); MELINO MICHAEL R (US)  
Priority (No,Kind,Date): GB 9617898 A 19960828; US 21420 P  
19960709; US 29351 P 19961031  
Applic (No,Kind,Date): WO 97US12426 A 19970703  
Designated States: (National) AL; AM; AU; AZ; BB; BG; BR; BY; CA; CN;  
CZ; EE; GE; HU; IL; IS; JP; KG; KR; KZ; LK; LR; LT; LV; MD; MG; MK;

MN; MX; NO; NZ; PL; RO; RU; SG; SI; SK; SL; TJ; TM; TR; TT; UA; US;  
UZ; VN; YU; AM; AZ; BY; KG; KZ; MD; RU; TJ; TM (Regional) GH; KE;  
LS; MW; SD; SZ; UG; ZW; AT; BE; CH; DE; DK; ES; FI; FR; GB; GR; IE;  
IT; LU; MC; NL; PT; SE; BF; BJ; CF; CG; CI; CM; GA; GN; ML; MR; NE;  
SN; TD; TG

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IPC: \* A61K-009/20

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Derwent WPI Acc No: \* C 98-110203; C 98-110207; C 98-145191; C  
98-110207

Language of Document: English

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METHOD FOR TREATING HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (English)

Patent Assignee: MERCK & CO INC (US); MITCHEL YALE B (US); TOBERT  
JONATHAN A (US)

Author (Inventor): MITCHEL YALE B (US); TOBERT JONATHAN A (US)

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19960709; US 29351 P 19961031

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CN; CU; CZ; EE; GE; HU; IL; IS; JP; KG; KR; KZ; LC; LK; LR; LT; LV;  
MD; MG; MK; MN; MX; NO; NZ; PL; RO; RU; SG; SI; SK; SL; TJ; TM; TR;  
TT; UA; US; UZ; VN; YU; AM; AZ; BY; KG; KZ; MD; RU; TJ; TM  
(Regional) GH; KE; LS; MW; SD; SZ; UG; ZW; AT; BE; CH; DE; DK; ES; FI  
; FR; GB; GR; IE; IT; LU; MC; NL; PT; SE; BF; BJ; CF; CG; CI; CM; GA;  
GN; ML; MR; NE; SN; TD; TG

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128(09)097715J

Derwent WPI Acc No: \* C 98-110203; C 98-110207; C 98-145191; C  
98-110203

Language of Document: English

Patent (No,Kind,Date): WO 9801119 A2 19980115

PHARMACEUTICAL COMPOSITIONS (English)

Patent Assignee: MERCK & CO INC (US); MITCHEL YALE B (US); TOBERT  
JONATHAN A (US)

Author (Inventor): MITCHEL YALE B (US); TOBERT JONATHAN A (US)

Priority (No,Kind,Date): GB 9617898 A 19960828; US 21420 P  
19960709; US 29351 P 19961031

Applic (No,Kind,Date): WO 97US10867 A 19970703

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CZ; EE; GE; HU; IL; IS; JP; KG; KR; KZ; LK; LR; LT; LV; MD; MG; MK;  
MN; MX; NO; NZ; PL; RO; RU; SG; SI; SK; SL; TJ; TM; TR; TT; UA; US;  
UZ; VN; YU; AM; AZ; BY; KG; KZ; MD; RU; TJ; TM (Regional) GH; KE;  
LS; MW; SD; SZ; UG; ZW; AT; BE; CH; DE; DK; ES; FI; FR; GB; GR; IE;  
IT; LU; MC; NL; PT; SE; BF; BJ; CF; CG; CI; CM; GA; GN; ML; MR; NE;  
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CA Abstract No: \* 128(09)097715J; 128(09)097716K; 128(11)132435S;  
128(11)132435S

Derwent WPI Acc No: \* C 98-110203; C 98-110207; C 98-145191; C

98-145191

Language of Document: English

WORLD INTELLECTUAL PROPERTY ORGANIZATION, PCT (WO)

Legal Status (No, Type, Date, Code, Text):

|            |   |  |            |   |
|------------|---|--|------------|---|
| WO 9801100 | P | 19960709   | WO AA      | PRIORITY CLAIMED  |
|            |   | US 21420   | P          | 19960709  |
| WO 9801100 | P | 19960828   | WO AA      | PRIORITY (PATENT)   |
|            |   | GB 9617898   | A          | 19960828  |
| WO 9801100 | P | 19961031   | WO AA      | PRIORITY CLAIMED  |
|            |   | US 29351   | P          | 19961031  |
| WO 9801100 | P | 19970703   | WO AE      | APPLICATION DATA (APPL. DATA)   |
|            |   | WO 97US11792   | A          | 19970703  |
| WO 9801100 | P | 19980115   | WO AK      | DESIGNATED STATES CITED IN A PUBLISHED APPLICATION WITHOUT SEARCH REPORT (DESIGNATED STATES CITED IN A PUBLISHED APPL. WITHOUT SEARCH REPORT)   |
|            |   | AL AM AU AZ BA BB BG BR BY CA CN CU CZ EE GE HU IL IS JP KG KR KZ LC LK LR LT LV MD MG MK MN MX NO NZ PL RO RU SG SI SK SL TJ TM TR TT UA US UZ VN YU AM AZ BY KG KZ MD RU TJ TM |            |   |
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|            |   | GH KE LS MW SD SZ UG ZW AT BE CH DE DK ES FI FR GB GR IE IT LU MC NL PT SE BF BJ CF CG CI CM GA GN ML MR NE SN TD TG   |            |   |
| WO 9801100 | P | 19980115   | WO A2      | PUBLICATION OF THE INTERNATIONAL APPLICATION WITHOUT THE INTERNATIONAL SEARCH REPORT (PUB. OF THE INTERNATIONAL APPL. WITHOUT THE INTERNATIONAL SEARCH REPORT)                                |
| WO 9801100 | P | 19980326   | WO DFPE    | REQUEST FOR PRELIMINARY EXAMINATION FILED PRIOR TO EXPIRATION OF 19TH MONTH FROM PRIORITY DATE  |
| WO 9801100 | P | 19980520   | WO 121     | EP: PCT APP. ART. 158 (1) (EP: PCT ANM. ART. 158 (1))   |
| WO 9801100 | P | 19990604   | WO NENP    | <u>NON-ENTRY INTO THE NATIONAL PHASE IN:</u>  |
|            |   | <u>JP</u>  | 1998505308 |   |
| WO 9801100 | P | 20000109   | WO NENP    | <u>NON-ENTRY INTO THE NATIONAL PHASE IN:</u>  |
|            |   | <u>CA</u>  |            |   |
| WO 9801100 | P | 20000209   | WO 122     | EP: PCT APP. NOT ENT. EUROP. PHASE (EP: PCT ANM. NICHT IN EUROP. PHASE <u>ENG.</u> )  |
| WO 9801116 | P | 19960709   | WO AA      | PRIORITY CLAIMED  |
|            |   | US 21420   | P          | 19960709  |
| WO 9801116 | P | 19960828   | WO AA      | PRIORITY (PATENT)   |
|            |   | GB 9617898   | A          | 19960828  |
| WO 9801116 | P | 19961031   | WO AA      | PRIORITY CLAIMED  |
|            |   | US 29351   | P          | 19961031  |
| WO 9801116 | P | 19970703   | WO AE      | APPLICATION DATA (APPL. DATA)   |

DATA)  
WO 97US12426 A 19970703

WO 9801116 P 19980115 WO AK DESIGNATED STATES CITED IN A  
PUBLISHED APPLICATION WITH SEARCH REPORT  
(DESIGNATED STATES CITED IN A PUBLISHED APPL.  
WITH SEARCH REPORT)  
AL AM AU AZ BB BG BR BY CA CN CZ EE GE HU IL  
IS JP KG KR KZ LK LR LT LV MD MG MK MN MX NO  
NZ PL RO RU SG SI SK SL TJ TM TR TT UA US UZ  
VN YU AM AZ BY KG KZ MD RU TJ TM

WO 9801116 P 19980115 WO AL DESIGNATED COUNTRIES FOR  
REGIONAL PATENTS CITED IN A PUBLISHED  
APPLICATION WITH SEARCH REPORT (DESIGNATED  
COUNTRIES FOR REGIONAL PATENTS CITED IN A  
PUBLISHED APPL. WITH SEARCH REPORT)  
GH KE LS MW SD SZ UG ZW AT BE CH DE DK ES FI  
FR GB GR IE IT LU MC NL PT SE BF BJ CF CG CI  
CM GA GN ML MR NE SN TD TG

WO 9801116 P 19980115 WO A1 PUBLICATION OF THE  
INTERNATIONAL APPLICATION WITH THE  
INTERNATIONAL SEARCH REPORT (PUB. OF THE  
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SEARCH REPORT)

WO 9801116 P 19980212 WO DFPE REQUEST FOR PRELIMINARY  
EXAMINATION FILED PRIOR TO EXPIRATION OF 19TH  
MONTH FROM PRIORITY DATE

WO 9801116 P 19980506 WO 121 EP: PCT APP. ART. 158 (1)  
(EP: PCT ANM. ART. 158 (1))

WO 9801116 P 19990604 WO NENP NON-ENTRY INTO THE NATIONAL  
PHASE IN:  
JP 1998505391

WO 9801116 P 20000109 WO NENP NON-ENTRY INTO THE NATIONAL  
PHASE IN:  
CA

WO 9801116 P 20000112 WO 122 EP: PCT APP. NOT ENT. EUROP.  
PHASE (EP: PCT ANM. NICHT IN EUROP. PHASE  
EING.)

WO 9801119 P 19960709 WO AA PRIORITY CLAIMED  
US 21420 P 19960709

WO 9801119 P 19960828 WO AA PRIORITY (PATENT)  
GB 9617898 A 19960828

WO 9801119 P 19961031 WO AA PRIORITY CLAIMED  
US 29351 P 19961031

WO 9801119 P 19970703 WO AE APPLICATION DATA (APPL.  
DATA)  
WO 97US10867 A 19970703

WO 9801119 P 19980115 WO AK DESIGNATED STATES CITED IN A  
PUBLISHED APPLICATION WITHOUT SEARCH REPORT  
(DESIGNATED STATES CITED IN A PUBLISHED APPL.  
WITHOUT SEARCH REPORT)  
AL AM AU AZ BB BG BR BY CA CN CZ EE GE HU IL  
IS JP KG KR KZ LK LR LT LV MD MG MK MN MX NO  
NZ PL RO RU SG SI SK SL TJ TM TR TT UA US UZ  
VN YU AM AZ BY KG KZ MD RU TJ TM

WO 9801119 P 19980115 WO AL DESIGNATED COUNTRIES FOR  
REGIONAL PATENTS CITED IN A PUBLISHED  
APPLICATION WITHOUT SEARCH REPORT



(DESIGNATED COUNTRIES FOR REGIONAL PATENTS  
CITED IN A PUBLISHED APPL. WITHOUT SEARCH  
REPORT)

GH KE LS MW SD SZ UG ZW AT BE CH DE DK ES FI  
FR GB GR IE IT LU MC NL PT SE BF BJ CF CG CI  
CM GA GN ML MR NE SN TD TG

|            |   |          |         |  |
|------------|---|----------|---------|--|
| WO 9801119 | P | 19980115 | WO A2   | PUBLICATION OF THE<br>INTERNATIONAL APPLICATION WITHOUT THE<br>INTERNATIONAL SEARCH REPORT (PUB. OF THE<br>INTERNATIONAL APPL. WITHOUT THE INTERNATIONAL<br>SEARCH REPORT) |
| WO 9801119 | P | 19980312 | WO DFPE | REQUEST FOR PRELIMINARY<br>EXAMINATION FILED PRIOR TO EXPIRATION OF 19TH<br>MONTH FROM PRIORITY DATE   |
| WO 9801119 | P | 19980506 | WO 121  | EP: PCT APP. ART. 158 (1)<br>(EP: PCT ANM. ART. 158 (1))   |
| WO 9801119 | P | 19990604 | WO NENP | <u>NON-ENTRY</u> INTO THE NATIONAL<br>PHASE IN:<br><u>JP 1998505217</u>  |
| WO 9801119 | P | 19991110 | WO 122  | <u>EP: PCT APP. NOT ENT. EUROP.</u><br>PHASE (EP: PCT ANM. NICHT IN EUROP. PHASE<br>EING.)   |
| WO 9801119 | P | 20000109 | WO NENP | <u>NON-ENTRY</u> INTO THE NATIONAL<br>PHASE IN:<br><u>CA</u>   |

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